PREMARKET NOTIFICATION [510(K)] SUMMARY

AUG 15 2008

Date Prepared:	August 11, 2008
Submitter:	St. Jude Medical, CRMD
Address:	701 E. Evelyn Avenue Sunnyvale, CA 94086
Phone:	408 522 6494
Fax:	408 522 6440
Contact Person:	Elisabeth E. Neely
Trade Name/Proprietary Name:	SJM Confirm Implantable Cardiac Monitor System
Common Name:	Implantable Cardiac Monitor Model Numbers: DM2100, DM2100A
Classification:	Class II, 21 CFR 870.2800, 21 CFR 870.2920
Legally marketed device to which your firm is claiming equivalence:	Medtronic Reveal Plus ILR K994331

Device Description:

The SJM Confirm Implantable Cardiac Monitor is a minimally invasive, implantable diagnostic monitoring device with subcutaneous electrodes that are used for sensing and a looping memory for storage of electrograms (EGM). The device is comprised of three main components: the implantable cardiac monitor (Model DM2100) and the external patient activator (Model DM2100A). The third component is the programmer the physician uses to communicate to the cardiac monitor and associated programmer software. The programmer is the legally marketed SJM Merlin PCS programmer Model 3650 (with Software Model 3330 Version 6.8.1 (or higher)).

The indication for use is as follows:

The SJM Confirm™ ICM is an implantable patient-activated and automatically-activated monitoring system that records subcutaneous ECG and is indicated in the following cases:

- patients with clinical syndromes or situations at increased risk of cardiac arrhythmias
- patients who experience transient symptoms that may suggest a cardiac arrhythmia

Technological Characteristics of the Device Compared to the Predicate Device:

The SJM Confirm ICM uses similar technology; has similar intended use, functions, materials and method of operation of the following predicate device described in Table 1 below.

Table 1: SJM Confirm ICM Compared to Predicate Device

Feature	SJM Confirm	Medtronic Reveal Plus
Subcutaneous ECG Recording	Yes	Yes
Pre and Post Event Storage	Yes	Yes
EGM Storage	33 minutes	21 minutes (without compression)
Sampling Rate	128 Hz	100 Hz
Dimensions (mm) Width	18 x 56 x 8	19 x 61 x 8
Volume	6.5 cc	8 cc
Weight	12 g	17 g
Electrode Spacing	39 mm	38.5 mm
Shelf life	12 months	14 months
Auto Activation Triggers	Yes	Yes
Manual (Patient) Activation Trigger	Yes	Yes
High Rate Trigger	Yes	Yes
Programmable High Rate Count	Yes	Yes
Low Rate Trigger	Yes	Yes
Asystole Trigger	Yes	Yes

Summary of Studies:

Verification and validation activities necessary to ensure that the SJM Confirm ICM product and system requirements were fulfilled, and to ensure that the product design conforms to the user needs and intended uses were identified and successfully performed. Product verification was successfully performed and is documented in the following reports:

Appendix 7.1	QTR2288: Confirm ICM Mechanical Test Report
Appendix 7.2	QTR2280: Confirm ICM Electrical Test Report
Appendix 7.3	QTR2286: Confirm ICM EMC Test Report
Appendix 7.4	QTR2267: Patient Activator Test Report
Appendix 7.5	Firmware SVRs
Appendix 7.6	QRS Detection Accuracy and AF Detection Algorithm Report
Appendix 7.7	System Validation Report
Appendix 7.8	GLP Study Report

Biocompatibility:

There is no change to the blood/tissue contact materials of the SJM Confirm ICM device as compared to legally marketed St. Jude Medical pacemakers and ICDs (e.g., Epic + ICD P910023/S65 and Affinity pacemaker P880086/S61). Therefore, no additional biocompatibility testing was considered necessary per ISO 10993-1. See Table 2 below.

Table 2: SJM Confirm ICM Patient Contact Materials

Component	Material	Trade Name of Material	Predicate SJM Device	PMA Number (Approval Date)
Can	Titanium (grade 1)	n/a	Epic + ICD, Atlas + ICD	P910023/S65 (4/23/03), P910023/S69 (10/17/03)
Header Electrode	Titanium (grade 1)	n/a	Epic + ICD, Atlas + ICD	P910023/S65 (4/23/03), P910023/S69 (10/17/03)
Header	Epoxy	Hysol High Purity Epoxy	Epic + ICD, Atlas + ICD	P910023/S65 (4/23/03), P910023/S69 (10/17/03)
Parylene Coat	Parylene	Parylene-C Conforming Coating polymer	Affinity SR	P880086/S61 (6/17/99)

Sterilization Validation:

The SJM Confirm ICM is sterilized using the same validated 100% Ethylene Oxide (EtO) sterilization process as legally marketed St. Jude Medical pacemakers. The sterility assurance level (SAL) is 10^{-6}. A sterilization assessment report is provided in **Appendix 6**. The patient activator, Model DM2100A, is not sterile.

Conclusion:

St. Jude Medical considers the SJM Confirm ICM system to be substantially equivalent to the legally marketed predicate and referenced device.

The results of the tests and compliance with applicable standards (reference Section 6) provide reasonable assurance that the device has been designed and tested to assure conformance to the requirements for its indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 15 2008

St. Jude Medical
c/o Ms. Elizabeth Neely
Regulatory Affairs
Cardiac Rhythm Management Division
701 East Evelyn Avenue
Sunnyvale, CA 94086

Re: K081365
Trade/Device Name: Confirm Model DM2100 Implantable Cardiac Monitor
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: Class II
Product Code: MXC, DSH, DXH
Dated: July 9, 2008
Received: July 10, 2008

Dear Ms. Neely:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

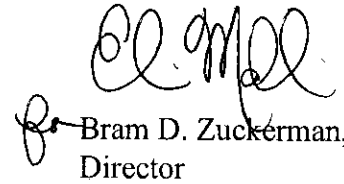
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807);

labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K081365

Device Name: Confirm Model DM2100 Implantable Cardiac Monitor

Indications For Use:
The SJM Confirm ICM is an implantable patient-activated and automatically-activated monitoring system that records subcutaneous ECG and is indicated in the following cases:

- patients with clinical syndromes or situations at increased risk of cardiac arrhythmias
- patients who experience transient symptoms that may suggest a cardiac arrhythmia

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K081365